DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 8 1997

Mr. Julian C. Green
Attorney & Counselor At Law
Willowbrook Place II
17350 S.H. 249, Suite #110
Houston Texas 77064

Re: 95A-0074/AP1

Dear Mr. Green:

This letter is in response to your March 9, 1995 request for an advisory opinion from the Food and Drug Administration (FDA) concerning whether silicone gel-filled breast prostheses submitted for entry by an individual for her personal use for augmentation surgery would be cleared for importation by FDA. The answer is no. For purposes of your question, the controlling policy is that announced by the agency on April 16, 1992, not just the import alert issued later that year as part of that policy's implementation. Entry is also not permissible under either FDA's personal use importation policy or the custom device provision of the law. Under FDA's April 16, 1992, breast implant policy, silicone gel-filled breast implants may be used for augmentation purposes in the United States only in accordance with FDA approved investigational device exemptions (IDEs). The background leading to this policy decision is described below.

On April 16, 1992, in response to applications for premarket approval, and following extensive deliberations including two public scientific Advisory Panel meetings, FDA announced its silicone gel-filled breast implant policy that remains in effect today. FDA denied approval of the applications with respect to use of the implants for augmentation. The agency extended the review period of the applications only with respect to the use of the implants for breast reconstruction. Accordingly, use of the implants for augmentation purposes is limited to women enrolled in clinical studies, under an approved IDE, designed to answer specific safety questions about the implants.

FDA implemented the breast implant policy in three stages. Stages one and two addressed the availability of silicone gel-filled breast prostheses to

95A-0074

AP A 1

women who would elect breast reconstruction because of cancer, or who have had serious trauma to a breast, or a disease or congenital disorder causing a severe breast abnormality. Stage three was the only stage to allow availability of silicone gel-filled breast implants for augmentation purposes, and that stage was limited to clinical studies under approved IDE's designed to answer specific safety questions about the frequency and severity of certain known adverse effects of the implants.

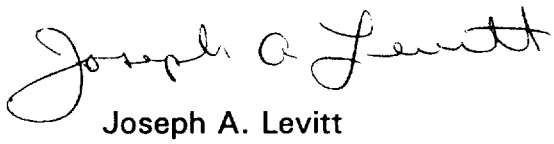
Under stage three clinical studies, manufacturers wishing to distribute silicone gel-filled breast prostheses for augmentation would need to meet the IDE requirements for significant risk devices as provided in 520(g) of the act (21 U.S.C. 360j(g)). An approved IDE permits a device that otherwise would be required to have marketing approval from FDA to be shipped lawfully for the purpose of conducting investigations of the device. An approved IDE is required to be in effect before an investigation of the device for augmentation use may be initiated or continued. To date, no manufacturers have received FDA approval of an IDE for use of silicone gel-filled breast implants for augmentation.

The other references you cite do not override this central policy on the use of these implants for breast augmentation. Import Alert 89-11, issued on December 2, 1992, prohibits importations of silicone implants for commercial distribution, but in no way is intended to sanction importation for personal use. FDA's personal use importation policy (Regulatory Procedures Manual, Chapter 9-71) does not apply here because: the device, when used for purposes of breast augmentation, is not intended to treat a serious medical condition; alternative devices (saline implants) are lawfully available; and the device presents potentially significant health risks for patients.

Finally, the custom device provision of the law that you cite is inapplicable because silicone gel-filled implants are generally manufactured overseas for a wide range of patients and not, therefore, made in a "specific form" for a particular patient nor intended to meet the "special needs" of an individual physician. Specifically, a particular size of a device otherwise available does not render the product a custom device.

In conclusion, domestic use of silicone gel-filled breast implants for augmentation purposes is restricted to clinical trials conducted under FDA-approved IDEs. Only women who are enrolled in such FDA-approved IDEs are eligible to receive silicone gel-filled breast implants for augmentation purposes. To date, no manufacturers have received FDA approval of an IDE for use of silicone gel-filled breast implants for augmentation. Therefore, no women are currently eligible to receive silicone gel-filled breast implants solely for augmentation purposes. To allow importation of such implants for personal use for augmentation surgery would be inconsistent with, and would undermine, this policy.

Sincerely yours,



Joseph A. Levitt
Deputy Director for
Regulations and Policy
Center for Devices and
Radiological Health